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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,178	07/17/2000	Stacey Efstathiou	5673-55696	8385

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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/05/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,178

Applicant(s)

EFSTATHIOU ET AL.

Examiner

Jessica H. Roark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 22-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendments, filed 5/1/02 (Paper No. 15), is acknowledged.

Claims 29-39 have been added.

Claims 17, 20, 24 and 28 have been amended.

Claims 1-16 and 21 have been cancelled previously.

Claims 17-20 and 22-39 are pending and under consideration.

2. Foreign priority document GB9916703, filed 8/24/01, appears to provide adequate written support for the instant claims 17-20, 22-27 and 29-39.

Applicant in the Response filed 5/1/02 directs the Examiner to page 2, lines 33-34 of GB9916703 for support for the limitation "coupled protein".

While it is acknowledged that binding of an M3 protein to a solid phase is supported, this specific description does not support the broader genus of the "coupled protein" of instant claim 28.

3. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.

Applicant's request, filed 5/1/02, to defer the filing of corrected formal drawing until allowance is acknowledged. However, the Office is no longer holding drawing corrections in abeyance.

Please see form PTO-948 previously provided as part of Paper No. 14.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

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4. Claims 24-26 and 28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. It is noted that in each of claims 24-26 and 28, the addition of a label or a coupled protein broadens, rather than limits the subject matter of claim 17.

Applicant's argument, filed 5/1/02, that the breadth of the terms "M3 protein" and "chemokine" encompass both unlabeled and labeled forms has been fully considered but has not been found convincing.

The specification does not appear to support Applicant's assertion that the terms "M3 protein" and chemokine encompass labeled forms of these molecules as no definition specifically encompassing these modified forms could be identified by the Examiner.

In addition, it is noted that the addition of a label appears to be drawn to *in vitro* uses, whereas a coupled protein appears to be drawn to *in vivo* uses. Applicant is again invited to consider providing claims that are structured to indicate this.

5. This Office Action will be in response to applicant's arguments, filed 5/1/02 (Paper No. 15). The rejections of record can be found in the previous Office Action (Paper No. 14).

It is noted that New Grounds of Rejection are set forth herein.

6. The previous rejection of claims 17-20 and 22-28 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment to specify that the M3 protein is the M3 protein of MHV68.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 17-20 and 22-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising contacting cells with the M3 protein of MHV68, does not reasonably provide enablement for the full breadth of an "M3 protein or functional homologue thereof". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Applicant's arguments, filed 5/1/02, have been fully considered but have not been found convincing, essentially for the reasons of record set forth in Paper No. 14.

Applicant submits that homologs of the M3 protein of MHV68 can be readily identified by one of skill in the art using the guidance provided in the specification with respect to binding assays which permit determination if a homolog of M3 binds a chemokine of interest. Applicant concludes that given such assays, one of skill in the art could readily identify M3 homologs for use in the instant methods.

However, guidance with respect to how to identify a homolog, once made, does not provide guidance as to how the skilled artisan should alter the M3 protein of MHV68 to make functional homologs thereof. Neither does it provide the skilled artisan with sufficient guidance as to which of the numerous proteins having at least about 20% homology (those proteins encompassed by the term homolog, as set forth in the bridging paragraph of pages 1-2) the skilled artisan should select to screen in the binding assay.

Although Applicant provides data showing that the M3 protein of MHV68 can bind to several chemokines, the specification does not appear to have established a structural basis for this function. Further, the state of the art did not recognize the structural attributes of the M3 protein needed to bind a chemokine and inhibit binding of the chemokine to its receptor. As previously noted, van Berkel et al. (J. Virol. 2000; 74: 6741-6747, of record) teach that the chemokine binding function of various viral proteins likely arose by convergent evolution, because proteins with this function are apparently *unrelated at the primary amino acid sequence level* (see especially page 6746, 3rd paragraph). Thus in the absence of some recognized structural basis for the function of chemokine binding, it would require undue experimentation of the skilled artisan to select other proteins having at least 20% homology that could then be screened for the desired function of binding a chemokine.

With respect to a homologue that is a variant of the M3 protein of MHV68, Applicant has not provided the skilled artisan with sufficient guidance as to the identity of residues to be changed, to be left unchanged, or to be deleted. Without clear direction and guidance as to the nature of the changes to be made to the reference M3 protein of MHV68; the skilled artisan would be faced with undue experimentation to produce the immense number of proteins encompassed by a "functional homologue thereof" and determine if there were any operative embodiments that would result in the recited functional activity of binding a chemokine and blocking the binding of the chemokine to its receptor.

Thus the Examiner maintains that the specification does not appear to provide the skilled artisan with sufficient guidance to make and use a "functional homologue thereof", commensurate in scope with the claimed invention. The Examiner further notes that an examiner is not prohibited from making a new grounds of rejection provided it is warranted during the prosecution of a patent application. In the instant case, the rejection set forth in Paper No. 14 appears to be applicable to the instant claims since there is insufficient biochemical or structural information to enable the skilled artisan to make and use the "functional homologue", as broadly claimed. Given the myriad structures encompassed by the term "functional homologue as set forth in the specification, such a recitation is essentially claiming in terms of function. However, "[i]t is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

Neither the amendment to further require that the M3 protein be an M3 protein from MHV68 or that the homologue thereof binds a chemokine alter the grounds of the rejection of record, as chemokine binding was already acknowledged to be a function possessed by the homologue.

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In addition, newly added claims 29-39 also do not alter the rejection of record since although they limit the claims to individual chemokines, the skilled artisan still would not have sufficient guidance as to changes that could be made that maintained binding to that chemokine nor direction as to which other proteins having at least about 20% homology should be screened to determine if they possessed this function.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The changes which can be made in the structure of the M3 protein of MHV68 and still provide or maintain the activity of binding a chemokine are unpredictable in view of the limited guidance provided in the specification. Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The rejection is maintained as applied to the amended and newly added claims.

9. The previous rejection of claims 17-20 and 22-28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of blocking binding of the chemokines lymphotactin, RANTES, MIP-1-(alpha), MCP-1, MCP-4, IL-8, hIP-10, fractalkine, and SLC; does not reasonably provide enablement for the full breadth of the phrase "a chemokine" is withdrawn.

Applicant's arguments that the specification provides working examples of each class of chemokines (C, CC, CXC and CXC3) and that the data regarding the murine CXC chemokines, does support at least some degree of competition as indicated by a reduced, although not absent, band in Figure 2, lanes 10, 13 and 14, is found convincing.

10. No claim is allowed.

11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
July 3, 2002

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